

# SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by  
UK REACH Regulations SI 2019/758



ORGANON

## Losartan Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 26.09.2023
4.2	06.04.2024	9825425-00007	Date of first issue: 12.10.2021

---

### SECTION 1: Identification of the substance/mixture and of the company/undertaking

#### 1.1 Product identifier

Trade name : Losartan Formulation

#### 1.2 Relevant identified uses of the substance or mixture and uses advised against

Use of the Sub-  
stance/Mixture : Pharmaceutical

Recommended restrictions  
on use : Not applicable

#### 1.3 Details of the supplier of the safety data sheet

Company : Organon & Co.  
Shotton Lane  
NE23 3JU Cramlington NU - Great Britain

Telephone : +44 1 670 59 32 05

E-mail address of person  
responsible for the SDS : EHSSTEWARD@organon.com

#### 1.4 Emergency telephone number

+1-215-631-6999

---

### SECTION 2: Hazards identification

#### 2.1 Classification of the substance or mixture

**Classification (REGULATION (EC) No 1272/2008) as amended by GB-CLP Regulation, UK  
SI 2019/720, and UK SI 2020/1567)**

Acute toxicity, Category 4	H302: Harmful if swallowed.
Serious eye damage, Category 1	H318: Causes serious eye damage.
Skin sensitisation, Category 1	H317: May cause an allergic skin reaction.
Reproductive toxicity, Category 1B	H360D: May damage the unborn child.
Effects on or via lactation	H362: May cause harm to breast-fed children.
Specific target organ toxicity - repeated exposure, Category 2	H373: May cause damage to organs through pro- longed or repeated exposure.

#### 2.2 Label elements

**Labelling (REGULATION (EC) No 1272/2008) as amended by GB-CLP Regulation, UK SI  
2019/720, and UK SI 2020/1567)**

# SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by  
UK REACH Regulations SI 2019/758



ORGANON

## Losartan Formulation

Version 4.2      Revision Date: 06.04.2024      SDS Number: 9825425-00007      Date of last issue: 26.09.2023  
Date of first issue: 12.10.2021

Hazard pictograms	:	
Signal word	:	Danger
Hazard statements	:	H302 Harmful if swallowed. H317 May cause an allergic skin reaction. H318 Causes serious eye damage. H360D May damage the unborn child. H362 May cause harm to breast-fed children. H373 May cause damage to organs through prolonged or repeated exposure.
Precautionary statements	:	<b>Prevention:</b> P201 Obtain special instructions before use. P260 Do not breathe dust. P263 Avoid contact during pregnancy and while nursing. P280 Wear protective gloves/ protective clothing/ eye protection/ face protection. <b>Response:</b> P305 + P351 + P338 + P310 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER/ doctor. P308 + P313 IF exposed or concerned: Get medical advice/ attention.

Hazardous components which must be listed on the label:  
Losartan

### 2.3 Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.  
Contact with dust can cause mechanical irritation or drying of the skin.  
May form explosive dust-air mixture during processing, handling or other means.

## SECTION 3: Composition/information on ingredients

### 3.2 Mixtures

#### Components

Chemical name	CAS-No. EC-No. Index-No. Registration number	Classification	Concentration (% w/w)
Losartan	124750-99-8	Acute Tox. 4; H302 Eye Dam. 1; H318 Skin Sens. 1; H317	>= 30 - < 50

# SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by  
UK REACH Regulations SI 2019/758



## Losartan Formulation

Version 4.2      Revision Date: 06.04.2024      SDS Number: 9825425-00007      Date of last issue: 26.09.2023  
Date of first issue: 12.10.2021

		Repr. 1B; H360D Lact.H362 STOT RE 2; H373 (Blood, Cardio-vascular system, Stomach, Kidney)	
Substances with a workplace exposure limit :			
Cellulose	9004-34-6 232-674-9		>= 30 - < 50
Starch	9005-25-8 232-679-6		>= 10 - < 20

For explanation of abbreviations see section 16.

### SECTION 4: First aid measures

#### 4.1 Description of first aid measures

- General advice : In the case of accident or if you feel unwell, seek medical advice immediately.  
When symptoms persist or in all cases of doubt seek medical advice.
- Protection of first-aiders : First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).
- If inhaled : If inhaled, remove to fresh air.  
Get medical attention.
- In case of skin contact : In case of contact, immediately flush skin with soap and plenty of water.  
Remove contaminated clothing and shoes.  
Get medical attention.  
Wash clothing before reuse.  
Thoroughly clean shoes before reuse.
- In case of eye contact : In case of contact, immediately flush eyes with plenty of water for at least 15 minutes.  
If easy to do, remove contact lens, if worn.  
Get medical attention immediately.
- If swallowed : If swallowed, DO NOT induce vomiting.  
Get medical attention.  
Rinse mouth thoroughly with water.  
Never give anything by mouth to an unconscious person.

#### 4.2 Most important symptoms and effects, both acute and delayed

- Risks : Harmful if swallowed.  
May cause an allergic skin reaction.  
Causes serious eye damage.

# SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by  
UK REACH Regulations SI 2019/758



ORGANON

## Losartan Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 26.09.2023
4.2	06.04.2024	9825425-00007	Date of first issue: 12.10.2021

---

May damage the unborn child.  
May cause harm to breast-fed children.  
May cause damage to organs through prolonged or repeated exposure.

Contact with dust can cause mechanical irritation or drying of the skin.

### 4.3 Indication of any immediate medical attention and special treatment needed

Treatment : Treat symptomatically and supportively.

---

## SECTION 5: Firefighting measures

### 5.1 Extinguishing media

Suitable extinguishing media : Water spray  
Alcohol-resistant foam  
Carbon dioxide (CO<sub>2</sub>)  
Dry chemical

Unsuitable extinguishing media : None known.

### 5.2 Special hazards arising from the substance or mixture

Specific hazards during fire-fighting : Avoid generating dust; fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard.  
Exposure to combustion products may be a hazard to health.

Hazardous combustion products : Carbon oxides  
Chlorine compounds  
Nitrogen oxides (NO<sub>x</sub>)

### 5.3 Advice for firefighters

Special protective equipment for firefighters : In the event of fire, wear self-contained breathing apparatus.  
Use personal protective equipment.

Specific extinguishing methods : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.  
Use water spray to cool unopened containers.  
Remove undamaged containers from fire area if it is safe to do so.  
Evacuate area.

---

## SECTION 6: Accidental release measures

### 6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions : Use personal protective equipment.  
Follow safe handling advice (see section 7) and personal pro-

---

# SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by  
UK REACH Regulations SI 2019/758



## Losartan Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 26.09.2023
4.2	06.04.2024	9825425-00007	Date of first issue: 12.10.2021

---

ective equipment recommendations (see section 8).

### 6.2 Environmental precautions

Environmental precautions : Avoid release to the environment.  
Prevent further leakage or spillage if safe to do so.  
Retain and dispose of contaminated wash water.  
If spillage enters rivers or watercourses, inform the Environment Agency (emergency telephone number 0800 807060).

### 6.3 Methods and material for containment and cleaning up

Methods for cleaning up : Sweep up or vacuum up spillage and collect in suitable container for disposal.  
Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air).  
Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration.  
Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable.  
Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

### 6.4 Reference to other sections

See sections: 7, 8, 11, 12 and 13.

---

## SECTION 7: Handling and storage

### 7.1 Precautions for safe handling

Technical measures : Static electricity may accumulate and ignite suspended dust causing an explosion.  
Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres.

Local/Total ventilation : If sufficient ventilation is unavailable, use with local exhaust ventilation.

Advice on safe handling : Avoid contact during pregnancy and while nursing.  
Do not get on skin or clothing.  
Do not breathe dust.  
Do not swallow.  
Do not get in eyes.  
Wash skin thoroughly after handling.  
Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment  
Keep container tightly closed.  
Minimize dust generation and accumulation.  
Keep container closed when not in use.  
Keep away from heat and sources of ignition.  
Take precautionary measures against static discharges.

# SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by  
UK REACH Regulations SI 2019/758



## Losartan Formulation

Version 4.2      Revision Date: 06.04.2024      SDS Number: 9825425-00007      Date of last issue: 26.09.2023  
Date of first issue: 12.10.2021

Hygiene measures : Do not eat, drink or smoke when using this product.  
Take care to prevent spills, waste and minimize release to the environment.  
: If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place. When using do not eat, drink or smoke. Contaminated work clothing should not be allowed out of the workplace.  
Wash contaminated clothing before re-use.

### 7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers : Keep in properly labelled containers. Store locked up. Keep tightly closed. Store in accordance with the particular national regulations.

Advice on common storage : Do not store with the following product types:  
Strong oxidizing agents  
Self-reactive substances and mixtures  
Organic peroxides  
Explosives  
Gases

### 7.3 Specific end use(s)

Specific use(s) : No data available

## SECTION 8: Exposure controls/personal protection

### 8.1 Control parameters

#### Occupational Exposure Limits

dust of any kind      10 mg/m<sup>3</sup>  
Value type (Form of exposure): TWA (Inhalable)  
Basis: GB EH40

4 mg/m<sup>3</sup>  
Value type (Form of exposure): TWA (Respirable fraction)  
Basis: GB EH40

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
Cellulose	9004-34-6	TWA (inhalable dust)	10 mg/m <sup>3</sup>	GB EH40
		TWA (Respirable dust)	4 mg/m <sup>3</sup>	GB EH40
		STEL (inhalable dust)	20 mg/m <sup>3</sup>	GB EH40
Losartan	124750-99-8	TWA	100 µg/m <sup>3</sup> (OEB 2)	Internal
Starch	9005-25-8	TWA (inhalable dust)	10 mg/m <sup>3</sup>	GB EH40
		TWA (Respirable dust)	4 mg/m <sup>3</sup>	GB EH40

# SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by  
UK REACH Regulations SI 2019/758



ORGANON

## Losartan Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 26.09.2023
4.2	06.04.2024	9825425-00007	Date of first issue: 12.10.2021

---

### 8.2 Exposure controls

#### Engineering measures

Minimize workplace exposure concentrations.  
Apply measures to prevent dust explosions.  
Ensure that dust-handling systems (such as exhaust ducts, dust collectors, vessels, and processing equipment) are designed in a manner to prevent the escape of dust into the work area (i.e., there is no leakage from the equipment).  
If sufficient ventilation is unavailable, use with local exhaust ventilation.

#### Personal protective equipment

Eye/face protection	:	Wear the following personal protective equipment: Chemical resistant goggles must be worn. If splashes are likely to occur, wear: Face-shield Equipment should conform to BS EN 166
Hand protection	:	
Material	:	Chemical-resistant gloves
Remarks	:	Choose gloves to protect hands against chemicals depending on the concentration and quantity of the hazardous substance and specific to place of work. Breakthrough time is not determined for the product. Change gloves often! For special applications, we recommend clarifying the resistance to chemicals of the aforementioned protective gloves with the glove manufacturer. Wash hands before breaks and at the end of workday.
Skin and body protection	:	Select appropriate protective clothing based on chemical resistance data and an assessment of the local exposure potential. Skin contact must be avoided by using impervious protective clothing (gloves, aprons, boots, etc).
Respiratory protection	:	If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection. Equipment should conform to BS EN 143
Filter type	:	Particulates type (P)

---

## SECTION 9: Physical and chemical properties

### 9.1 Information on basic physical and chemical properties

Appearance	:	powder
Colour	:	White to light yellow
Odour	:	No data available
Odour Threshold	:	No data available
pH	:	No data available
Melting point/freezing point	:	No data available

# SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by  
UK REACH Regulations SI 2019/758



ORGANON

## Losartan Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 26.09.2023
4.2	06.04.2024	9825425-00007	Date of first issue: 12.10.2021

---

Initial boiling point and boiling range	:	No data available
Flash point	:	No data available
Evaporation rate	:	No data available
Flammability (solid, gas)	:	May form explosive dust-air mixture during processing, handling or other means.
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
Vapour pressure	:	No data available
Relative vapour density	:	No data available
Relative density	:	No data available
Density	:	1 g/cm <sup>3</sup>
Solubility(ies)		
Water solubility	:	No data available
Partition coefficient: n-octanol/water	:	No data available
Auto-ignition temperature	:	No data available
Decomposition temperature	:	No data available
Viscosity		
Viscosity, kinematic	:	No data available
Explosive properties	:	Not explosive
Oxidizing properties	:	The substance or mixture is not classified as oxidizing.

### 9.2 Other information

Flammability (liquids)	:	No data available
Molecular weight	:	No data available
Minimum ignition energy	:	> 300 mJ
Particle size	:	No data available



# SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by  
UK REACH Regulations SI 2019/758



## Losartan Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 26.09.2023
4.2	06.04.2024	9825425-00007	Date of first issue: 12.10.2021

---

### SECTION 10: Stability and reactivity

#### 10.1 Reactivity

Not classified as a reactivity hazard.

#### 10.2 Chemical stability

Stable under normal conditions.

#### 10.3 Possibility of hazardous reactions

Hazardous reactions : May form explosive dust-air mixture during processing, handling or other means.  
Can react with strong oxidizing agents.

#### 10.4 Conditions to avoid

Conditions to avoid : Heat, flames and sparks.  
Avoid dust formation.

#### 10.5 Incompatible materials

Materials to avoid : Oxidizing agents

#### 10.6 Hazardous decomposition products

No hazardous decomposition products are known.

---

### SECTION 11: Toxicological information

#### 11.1 Information on toxicological effects

Information on likely routes of exposure : Inhalation  
Skin contact  
Ingestion  
Eye contact

#### Acute toxicity

Harmful if swallowed.

#### Product:

Acute oral toxicity : Acute toxicity estimate: 1,502 mg/kg  
Method: Calculation method

#### Components:

##### Losartan:

Acute oral toxicity : LD50 (Mouse): 1,257 - 1,590 mg/kg  
LDLo (Rat): 200 mg/kg  
LDLo (Mouse): 400 mg/kg

##### Cellulose:

Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg

---

# SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by  
UK REACH Regulations SI 2019/758



## Losartan Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 26.09.2023
4.2	06.04.2024	9825425-00007	Date of first issue: 12.10.2021

---

Acute inhalation toxicity : LC50 (Rat): > 5.8 mg/l  
Exposure time: 4 h  
Test atmosphere: dust/mist

Acute dermal toxicity : LD50 (Rabbit): > 2,000 mg/kg

### Starch:

Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg

Acute dermal toxicity : LD50 (Rabbit): > 2,000 mg/kg

### Skin corrosion/irritation

Not classified based on available information.

### Components:

#### Losartan:

Species : Rabbit  
Result : Mild skin irritation

### Serious eye damage/eye irritation

Causes serious eye damage.

### Components:

#### Losartan:

Species : Rabbit  
Result : Severe irritation

#### Starch:

Species : Rabbit  
Result : No eye irritation

### Respiratory or skin sensitisation

#### Skin sensitisation

May cause an allergic skin reaction.

#### Respiratory sensitisation

Not classified based on available information.

### Components:

#### Losartan:

Test Type : Maximisation Test  
Exposure routes : Skin contact  
Species : Guinea pig  
Assessment : Probability or evidence of skin sensitisation in humans  
Result : positive

# SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by  
UK REACH Regulations SI 2019/758



## Losartan Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 26.09.2023
4.2	06.04.2024	9825425-00007	Date of first issue: 12.10.2021

---

### Starch:

Test Type	: Maximisation Test
Exposure routes	: Skin contact
Species	: Guinea pig
Result	: negative

### Germ cell mutagenicity

Not classified based on available information.

### Components:

#### Losartan:

Genotoxicity in vitro	: Test Type: in vitro assay Result: negative
	Test Type: In vitro mammalian cell gene mutation test Test system: Chinese hamster ovary cells Result: negative
	Test Type: Alkaline elution assay Result: negative
	Test Type: Chromosomal aberration Result: negative
Genotoxicity in vivo	: Test Type: Chromosomal aberration Result: negative

#### Cellulose:

Genotoxicity in vitro	: Test Type: Bacterial reverse mutation assay (AMES) Result: negative
	Test Type: In vitro mammalian cell gene mutation test Result: negative
Genotoxicity in vivo	: Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay) Species: Mouse Application Route: Ingestion Result: negative

#### Starch:

Genotoxicity in vitro	: Test Type: Bacterial reverse mutation assay (AMES) Result: negative
-----------------------	--

### Carcinogenicity

Not classified based on available information.

# SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by  
UK REACH Regulations SI 2019/758



ORGANON

## Losartan Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 26.09.2023
4.2	06.04.2024	9825425-00007	Date of first issue: 12.10.2021

---

### Components:

#### **Losartan:**

Species	:	Mouse
Application Route	:	Oral
Exposure time	:	92 weeks
Dose	:	200 mg/kg body weight
Result	:	negative

Species	:	Rat
Application Route	:	Oral
Exposure time	:	105 weeks
Dose	:	270 mg/kg body weight
Result	:	negative

#### **Cellulose:**

Species	:	Rat
Application Route	:	Ingestion
Exposure time	:	72 weeks
Result	:	negative

### **Reproductive toxicity**

May damage the unborn child.  
May cause harm to breast-fed children.

### Components:

#### **Losartan:**

Effects on fertility	:	Test Type: Fertility Species: Rat, female Application Route: Oral Fertility: LOAEL: 200 mg/kg body weight Result: female reproductive effects Remarks: Maternal toxicity observed.
Effects on foetal development	:	Test Type: Development Species: Rabbit Application Route: Oral General Toxicity Maternal: NOAEL: 10 mg/kg body weight Developmental Toxicity: NOAEL F1: 20 mg/kg body weight Result: Embryotoxic effects and adverse effects on the offspring were detected only at high maternally toxic doses, No teratogenic effects  Test Type: Development Species: Rat Application Route: Oral Developmental Toxicity: LOAEL: 10 mg/kg body weight Result: Fetotoxicity, No teratogenic effects
Reproductive toxicity - Assessment	:	Clear evidence of adverse effects on development, based on animal experiments.

# SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by  
UK REACH Regulations SI 2019/758



## Losartan Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 26.09.2023
4.2	06.04.2024	9825425-00007	Date of first issue: 12.10.2021

---

Studies indicating a hazard to babies during the lactation period

### Cellulose:

Effects on fertility : Test Type: One-generation reproduction toxicity study  
Species: Rat  
Application Route: Ingestion  
Result: negative

Effects on foetal development : Test Type: Fertility/early embryonic development  
Species: Rat  
Application Route: Ingestion  
Result: negative

### STOT - single exposure

Not classified based on available information.

### STOT - repeated exposure

May cause damage to organs through prolonged or repeated exposure.

### Components:

#### Losartan:

Exposure routes : Ingestion  
Target Organs : Blood, Cardio-vascular system, Stomach, Kidney  
Assessment : May cause damage to organs through prolonged or repeated exposure.

### Repeated dose toxicity

### Components:

#### Losartan:

Species : Rat  
LOAEL : 15 mg/kg  
Application Route : Oral  
Exposure time : 309 d  
Number of exposures : daily  
Target Organs : Blood, Kidney, Cardio-vascular system, Stomach

Species : Dog  
NOAEL : 5 mg/kg  
Application Route : Oral  
Exposure time : 1 Months  
Symptoms : Salivation, Vomiting

Species : Dog  
LOAEL : 25 mg/kg  
Application Route : Oral  
Exposure time : 53 Weeks  
Number of exposures : daily

# SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by  
UK REACH Regulations SI 2019/758



## Losartan Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 26.09.2023
4.2	06.04.2024	9825425-00007	Date of first issue: 12.10.2021

---

Symptoms : Salivation, Vomiting

### Cellulose:

Species : Rat  
NOAEL :  $\geq 9,000$  mg/kg  
Application Route : Ingestion  
Exposure time : 90 Days

### Starch:

Species : Rat  
NOAEL :  $\geq 2,000$  mg/kg  
Application Route : Skin contact  
Exposure time : 28 Days  
Method : OECD Test Guideline 410

### Aspiration toxicity

Not classified based on available information.

### Components:

#### Losartan:

No aspiration toxicity classification

### Experience with human exposure

### Components:

#### Losartan:

Eye contact : Symptoms: Eye irritation  
Ingestion : Symptoms: hypotension, tachycardia

---

## SECTION 12: Ecological information

### 12.1 Toxicity

### Components:

#### Losartan:

Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)):  $> 929$  mg/l  
Exposure time: 96 h  
Method: FDA 4.11

Toxicity to daphnia and other : EC50 (Daphnia magna (Water flea)): 331 mg/l  
aquatic invertebrates : Exposure time: 48 h  
Method: OECD Test Guideline 202

Toxicity to algae/aquatic : NOEC (Microcystis aeruginosa (blue-green algae)): 949 mg/l  
plants : Exposure time: 10 d  
Method: FDA 4.01

NOEC (Selenastrum capricornutum (green algae)): 143 mg/l

---

# SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by  
UK REACH Regulations SI 2019/758



ORGANON

## Losartan Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 26.09.2023
4.2	06.04.2024	9825425-00007	Date of first issue: 12.10.2021

---

Exposure time: 10 d  
Method: FDA 4.01

Toxicity to fish (Chronic toxicity) : NOEC: 10 mg/l  
Exposure time: 32 d  
Species: Pimephales promelas (fathead minnow)  
Method: OECD Test Guideline 210

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC: 100 mg/l  
Exposure time: 21 d  
Species: Daphnia magna (Water flea)  
Method: OECD Test Guideline 211

### Cellulose:

Toxicity to fish : LC50 (Oryzias latipes (Japanese medaka)): > 100 mg/l  
Exposure time: 48 h  
Remarks: Based on data from similar materials

## 12.2 Persistence and degradability

### Components:

#### Losartan:

Stability in water : Hydrolysis: < 10 %(5 d)

#### Cellulose:

Biodegradability : Result: Readily biodegradable.

## 12.3 Bioaccumulative potential

### Components:

#### Losartan:

Partition coefficient: n-octanol/water : log Pow: 1.2

## 12.4 Mobility in soil

No data available

## 12.5 Results of PBT and vPvB assessment

### Product:

Assessment : This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

## 12.6 Other adverse effects

### Product:

Endocrine disrupting poten- : This substance/mixture does not contain components consid-

# SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



## Losartan Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 26.09.2023
4.2	06.04.2024	9825425-00007	Date of first issue: 12.10.2021

... is considered to have endocrine disrupting properties for environment according to UK REACH Article 57(f).

### SECTION 13: Disposal considerations

#### 13.1 Waste treatment methods

**Product** : Dispose of in accordance with local regulations. According to the European Waste Catalogue, Waste Codes are not product specific, but application specific. Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities. Do not dispose of waste into sewer.

**Contaminated packaging** : Empty containers should be taken to an approved waste handling site for recycling or disposal. If not otherwise specified: Dispose of as unused product.

### SECTION 14: Transport information

#### 14.1 UN number

**ADN** : Not regulated as a dangerous good  
**ADR** : Not regulated as a dangerous good  
**RID** : Not regulated as a dangerous good  
**IMDG** : Not regulated as a dangerous good  
**IATA** : Not regulated as a dangerous good

#### 14.2 UN proper shipping name

**ADN** : Not regulated as a dangerous good  
**ADR** : Not regulated as a dangerous good  
**RID** : Not regulated as a dangerous good  
**IMDG** : Not regulated as a dangerous good  
**IATA** : Not regulated as a dangerous good

#### 14.3 Transport hazard class(es)

**ADN** : Not regulated as a dangerous good  
**ADR** : Not regulated as a dangerous good  
**RID** : Not regulated as a dangerous good  
**IMDG** : Not regulated as a dangerous good  
**IATA** : Not regulated as a dangerous good

#### 14.4 Packing group

**ADN** : Not regulated as a dangerous good  
**ADR** : Not regulated as a dangerous good



# SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



ORGANON

## Losartan Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 26.09.2023
4.2	06.04.2024	9825425-00007	Date of first issue: 12.10.2021

**RID** : Not regulated as a dangerous good

**IMDG** : Not regulated as a dangerous good

**IATA (Cargo)** : Not regulated as a dangerous good

**IATA (Passenger)** : Not regulated as a dangerous good

### 14.5 Environmental hazards

Not regulated as a dangerous good

### 14.6 Special precautions for user

Not applicable

### 14.7 Transport in bulk according to Annex II of Marpol and the IBC Code

Remarks : Not applicable for product as supplied.

## SECTION 15: Regulatory information

### 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

Relevant EU provisions transposed through retained EU law

UK REACH List of restrictions (Annex 17) : Not applicable

UK REACH Candidate list of substances of very high concern (SVHC) for Authorisation : Not applicable

The Persistent Organic Pollutants Regulations (retained Regulation (EU) 2019/1021 as amended for Great Britain) : Not applicable

Regulation (EC) No 1005/2009 on substances that deplete the ozone layer : Not applicable

UK REACH List of substances subject to authorisation (Annex XIV) : Not applicable

GB Export and import of hazardous chemicals - Prior Informed Consent (PIC) Regulation : Not applicable

Control of Major Accident Hazards Regulations 2015 (COMAH) : Not applicable

#### Other regulations:

Take note of The Management of Health and Safety at Work Regulations 1999 (requirements relating to new and expectant mothers at work contained in Regulation 16 to 18) and of the Pregnant Workers Directive 92/85/EEC.

Take note of The Management of Health and Safety at Work Regulations 1999 (requirements relating to protection of young people at work contained in Regulation 19) and of Directive 94/33/EC on the protection of young people at work.

#### The components of this product are reported in the following inventories:

AICS : not determined

DSL : not determined

IECSC : not determined

# SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by  
UK REACH Regulations SI 2019/758



ORGANON

## Losartan Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 26.09.2023
4.2	06.04.2024	9825425-00007	Date of first issue: 12.10.2021

### 15.2 Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

### SECTION 16: Other information

Other information : Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

#### Full text of H-Statements

H302 : Harmful if swallowed.  
H317 : May cause an allergic skin reaction.  
H318 : Causes serious eye damage.  
H360D : May damage the unborn child.  
H362 : May cause harm to breast-fed children.  
H373 : May cause damage to organs through prolonged or repeated exposure if swallowed.

#### Full text of other abbreviations

Acute Tox. : Acute toxicity  
Eye Dam. : Serious eye damage  
Lact. : Effects on or via lactation  
Repr. : Reproductive toxicity  
Skin Sens. : Skin sensitisation  
STOT RE : Specific target organ toxicity - repeated exposure  
GB EH40 : UK. EH40 WEL - Workplace Exposure Limits  
GB EH40 / TWA : Long-term exposure limit (8-hour TWA reference period)  
GB EH40 / STEL : Short-term exposure limit (15-minute reference period)

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - Agreement concerning the International Carriage of Dangerous Goods by Road; AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative)

# SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by  
UK REACH Regulations SI 2019/758



ORGANON

## Losartan Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 26.09.2023
4.2	06.04.2024	9825425-00007	Date of first issue: 12.10.2021

tative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of very high concern; TCSI - Taiwan Chemical Substance Inventory; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative

### Further information

Sources of key data used to compile the Safety Data Sheet : Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, <http://echa.europa.eu/>

### Classification of the mixture:

Acute Tox. 4	H302
Eye Dam. 1	H318
Skin Sens. 1	H317
Repr. 1B	H360D
Lact.	H362
STOT RE 2	H373

### Classification procedure:

Calculation method
Calculation method
Calculation method
Calculation method
Calculation method
Calculation method

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user's end product, if applicable.

GB / EN